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Second Meeting of the Advisory Panel
on Preventive Medicine
Bogota, Colombia

22-23 November 1984

R E P O R T *

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P R E F A C E

UNIDO has established an Advisory Panel on Preventive Medicine in order to build up and implement a programme on the Industrial Production of Bio - logicals (IPB). The first Meeting of the Advisory Panel on Preventive Medicine was held in Vienna, Austria, from 27 to 28 February, 1984.

The conclusions and recommendations given by the Panel are in line with those in Issue 4: Biologicals of the Second Consultation on the Pharmaceutical Industry held in Budapest, Hungary in 1983 (UNIDO/ID/311, paras. 17 to 20).

Based on the recommendations of the Panel the UNIDO Secretariat start- ed to prepare a model programme for production of vaccines in developing countries as the basic technical documentation of IPB programme. Parallelly, the implementation of a technical assistance programme in the field of bio- logicals commenced in 1984. Based on a further recommendation of the Panel, a sub-account of UNIDF has been established to finance the implementation of the IPB programme.

The Advisory Panel on Preventive Medicine met in Bogota, Colombia from 22 to 23 November, 1984 in order to review the programmes of UNIDO's IPB programme in accordance with the recommendations of the First Meeting of the Panel held in Vienna in February 1984.

I. ORGANISATION OF THE MEETING

Opening of the Meeting

1. The meeting was opened by Dr. Charles Mérieux, Chairman of the Panel. In his inaugural address he stressed the importance of the IPB programme of UNIDO, the need to create technical capabilities and infrastructure for production of biologicals in developing countries and the need for co-operation among the members in order to successfully carry out the tasks assigned to the Panel. He expressed his regret on account of the absence of the representatives of WHO Headquarters and UNICEF and welcomed the representative of the Scientific, Technical and Research Commission of Organization for African Unity (OAU).

The UNIDO Secretariat's Presentation to the Advisory Panel

2. Ms. A. Tcheknavorian, Officer-in-Charge of the Chemical Industries Branch, Division of Industrial Operations and Chairperson of the Task Force on the Pharmaceutical Industry, UNIDO conveyed the heartfelt greetings of Dr. Abd-El Rahman Khane, Executive Director of UNIDO to the members of the Panel. She highlighted that the strategy of the IPB programme is based on an industrial approach characterised by the concept of unit process and homogenous culture system. This approach also secures the consistency in the consecutive production batches by means of a built-in quality assurance. It advocates the required transfer of technology through a long-term support programme to make the recipient enable to adopt and assimilate the technology but also to assist in the promotion of new products. In her presentation she emphasized that the industrial approach for production of bio - logicals in developing countries is only one of the possible alternatives to strengthen the primary health care by local supply of these particular products. If requested, UNIDO intends to develop technical assistance projects for demonstrative purposes for those developing countries which are in the phase of decision making. UNIDO

is ready to implement these projects jointly with other UN agencies or with the industry of developed and developing countries.

Since in many African countries there is a lack of capability, UNIDO will make all possible efforts to serve these regions; not only by starting the manufacture of conventional vaccines but also by controlling them. The first phase of this programme in Africa should be focused on the manpower development in any of the few well established African manufacturers. This approach would have the obvious advantage that the trainees would be familiarized with the production technology and quality control methods in similar or at least comparable cultural and environmental conditions as those in their home countries.

The Agenda of the Meeting

3. The agenda was as follows : (i) opening of the meeting, (ii) adoption of the report on the first meeting of the Panel, (iii) adoption of the terms of reference of the Panel, (iv) discussions on the model programme for production of vaccines in developing countries, (v) discussions on the programme for production of vaccines in Africa, (vi) conclusions and recommendations of the meeting and (vii) date of the next meeting.

Adoption of Documents of the IPB Programme

4. During the two-days meeting the Panel approved the Report of the First Meeting (UNIDO/IO.583 dated 9 June 1984) and the revised Terms of Reference.

The Terms of Reference of the Advisory Panel on Preventive Medicine (Industrial Production of Biologicals) is given as Annex 1.

Documentation

5. Working papers for the meeting were as follows:

(i) Model Programme for Production of Vaccines in Developing Countries, First draft, UC/GLO/84/120.

(ii) Programme and Requirements for Production of Biologicals in Developing Countries, Project Document, UC/GLO/84/118.

(iii) Programme for Production of Vaccines in Africa, Executive Summary, UC/RAF/83/088.

II. CONCLUSIONS AND RECOMMENDATIONS

6. The Panel recognised the importance of providing information on technological and financial aspects required for the establishment of the industrial production of biologicals and discussed the working paper UC/GLO/84/120 which described a model programme for the preparation of the BCG vaccine, pertussis vaccine, purified diphtheria toxoid, purified tetanus toxoid; the control required for these vaccines and also those for cell culture rabies vaccine, measles vaccine, inactivated poliomyelitis vaccine; with additional notes on buildings and services, staff members and qualitifications, equipment, maintenance and costs. The Panel accepted this first draft and recommended that additional sections be drafted including more detailed reference to training, animal accomodation, quality control, chemical engineering, local constraints, management, maintencance, priority criteria and cost effectiveness.

7. The Panel members agreed that they would forward their comments on the text by the end of January 1985. The second draft will be distributed by the end of March including an introduction and brief summary for further comments prior to the preparation of the final report for consideration at the third meeting.

8. Following the discussion on the working paper UC/GLO/84/120, the Panel recommended that a study be initiated by UNIDO on specifications of biological production equipment, their source and price and also on the provision of production units which are less capital intensive.

9. The Panel received Project Number UC/GLO/84/118/Revision 1 and recommended its implementation.

10. The Panel discussed the working paper on the Programme for Production of Vaccines in Africa, UC/RAF/83/088. Major topics considered included the need for political support involving regional and subregional organizations, the necessity of having accurate information of number of dosis required of the various vaccines, assurance of their purchase and the question of preference for locally and regionally manufactured

products provided quality is adequate. The Panel recommended that, in collaboration with other UN Agencies, UNIDO organizes regional or sub-regional meetings in Africa including the involvement of African regional organizations, Ministers of Health and producers of biological products in Africa. The Panel recommended that this consideration of the production of vaccines should be expanded to include diagnostic agents, culture media, blood products, and infusion solutions.

11. The Panel recommended that UNIDO responds positively to requests for rehabilitation/expansion of existing production and control facilities in Africa coupled with discussion with other UN Agencies, such as WHO and UNICEF and bilateral aid organizations on the prior need for assured utilisation of the manufactured biologicals by their attention being given to local and regional purchase of products meeting international standards even if their prices are slightly higher.

12. The Panel recommended a more comprehensive approach to the production of biologicals in Africa and take into consideration of Lagos Plan of Action by the establishment of an international development plan for African States based on the working paper UC/GLO/84/120. To effect such a plan UNIDO should take the lead.

13. Recognising the valuable contribution of the Executive Secretary of the Scientific, Technical and Research Commission of the Organisation for African Unity to the Panel's discussion, the Panel recommended that the holder of this office be invited to be a member of this Advisory Panel on Preventive Medicine.

14. Following the discussion of the situation in Africa, the Panel recommended that UNIDO, in collaboration with other UN Agencies, should initiate activities in the countries of Latin America, the Caribbean and Asia, using the principles outlined above, modified to their particular situations.

15. The Panel stressed the importance and acknowledged the establishment of an IPB fund. For further development and successful implementation of the IPB programme, the Panel recommended that UNIDO initiates fund

raising activities. Contributions should be secured from UN and other international Agencies, bilateral aid organizations and interested governments.

16. The Panel recommended the strengthening of collaboration in all aspects amongst UN agencies responsible for handling biologicals in order to facilitate the IPB programme.

17. The Panel recommended that its Third Meeting should be held no later than June 1985.

III. SUMMARY OF THE DISCUSSIONS

18. The report of the First Meeting of the Panel was discussed in length and it was agreed that the contribution of UNIDO through its IPB programme is fundamental for developing countries in assisting them to create technological capabilities and infrastructure and to develop trained manpower. The Panel emphasized the importance of strengthening the co-operation in all aspects among UN Agencies responsible for biologicals in order to promote the IPB. For many years WHO and UNICEF have been making efforts to achieve a higher coverage of immunization in developing countries with global programmes such as the Expanded Programme on Immunization (EPI), the Global Quality Assurance Certification Scheme, the Action Programme of Essential Drugs and Vaccines together with the Programme for Control of Diarrhoeal Diseases. UNICEF has initiated the GOBI programme including a low cost of immunization.

19. Since the First Meeting of the Panel in February 1984, only a little progress has been achieved in this aspect, however, a recent meeting at a high political level between WHO and UNIDO held in Geneva in November 1984, may give a momemtum. This meeting agreed that a WHO/UNIDO Technical Committee should be established and meet in 1985 to elaborate a working programme for co-operation and to describe responsibilities.

20. The Secretary of the Panel reminded its members that Dr. F.T. Perkins, Chief of Biologicals, WHO, who helped to find the final formulation of the issue and background papers entitled "The Manufacture of Vaccines in Developing Countries" (UNIDO/ID/WG.393/12/Rev.1 and ID/WG.393/13/Rev. 1) prepared for the Second Consultation on the Pharmaceutical Industry held in Budapest, Hungary in November 1983 and who actively participated in the First Meeting of the Panel, passed away. He could have different opinions in many cases she said in a short obituary, his zeal was driving and challenging all colleagues in the field of biologicals. His death was a great loss also for the Advisory Panel on Preventive Medicine.

21. A member of the Panel expressed concern that UNIDO was not invited to participate in the Bellagio Conference on the Protection of the World's Children, held in March 1984. He felt that the work of the Panel is beneficial to the world's community and therefore UNIDO should have been a participant of the above conference. Furthermore, he expressed his Government's particular concern for implementation of the recommendation under para 17 of the First Meeting of the Panel (UNIDO/IO.583 para 17, p.6).

22. The member from PAHO stated that several projects concerning manufacture of biologicals have been implemented by them, at national and regional levels, in Latin America. However, he said that UNIDO could develop a programme to increase the production of biologicals by an industrial approach to the existing manufacturers.

23. Another member emphasized the importance of the recommendations under para 22 of the First Meeting of the Panel (UNIDO/IO.583, para 22, p.6) and stated that FAO should be invited to become a member of the Panel.

24. After a lenghtly discussion the Panel adopted the Report of the First Meeting (UNIDO/IO.583) without changes and agreed that the conclusions and recommendations of the Report are in line with those of the Second Consultation on the Pharmaceutical Industry (UNIDO/ID/311). The Terms of Reference of the Advisory Panel on Preventive Medicine (Industrial Production of Biologicals) was adopted with a revised para 2.3 which was changed as follows :

"The Panel shall meet at least twice a year and as frequently as the exigencies of its work indicate, consistent with the availability of its membership" (Annex 1).

25. The Panel recommended in its first meeting (UNIDO/IO.583, para 12, p.5) that UNIDO with the advice of the members of the Panel should start the preparation of a master plan (Model Programme, as it is called now) for those projects on an industrial production of vaccines in developing countries. It was also recommended, that such a model programme

including techno-economic details, should be flexible for the implementation of such projects, at different stages, with regard to the development of the pharmaceutical industry in particular, and the industrial capability in general, in different developing countries. By accepting the generous offer given by Dr. H. H. Cohen, Director General, Dutch National Institute of Public Health and Environmental Hygiene in the first meeting of the Panel, the preparation of the "Model Programme for the Production of Vaccines in Developing Countries" under project No. UC/GLO/84/120 was progressing well. According to the UNIDO Secretariat's evaluation, the Model Programme is far behind from being complete. Nevertheless, the chapters of general introduction, vaccine production technology and quality control are in line with the objectives of this exercise. It was emphasized that the description of the production of purified tetanus toxoid is excellent because it does not only give the most important technological details and parameters for the industrial production but also provides details on such ill-defined manufacturing steps as the selection of high toxin yielding strain and determination of the optimal concentration of tryptic digest of casein (NZ-case) for each new batch. It was noted that chapters on the production of viral vaccines, economic aspects of vaccine production and control, as well as buildings and equipment have not yet been prepared.

26. The first draft of the Model Programme was discussed at length. The Panel agreed that the document even in its draft form is the most constructive and useful paper. It was stated that the most important new element of the document is the introduction of the multipurpose plant concept for production of biologicals. The Model Programme represents a unique offer for transfer of technology from an institution which itself not only has a long experience but also is successful in the industrial production of BCG vaccine, pertussis vaccine, purified diptheria toxoid, purified tetanus toxoid, inactivated polyomyelitis vaccine, measles vaccine and rabies vaccine.
The Panel agreed that the additional, under preparation, sections of the Model Programme should include more details on infrastructural requirements such as trained manpower, animal facilities, specification of laboratory animals, specification and maintenance requirements of equipment and costs of products. It was agreed that the general

introduction should contain more detailed reference to the qualified human resources, environmental and cultural conditions and economic aspects.

27. A member suggested to elaborate a separate document describing the production facilities at different technological levels, characterized by technologies less sophisticated than those been included in the Model Programme. Several members of the Panel stressed the fact that a study should be initiated by UNIDO,on alternative sources of biological production equipment which were included in the Model Programme, about their specifications and indicative prices and also on the prefabricated production units which are less capital intensive.

28. The member of PAHO while stressing the importance of the identification of those readers to whom the Model Programme will be addressed, suggested that the document should be commented by the manufacturers in the developing countries. According to his view, the document will be a useful tool in increasing the efficiency of the existing biological producers in the developing countries.

29. The representative of OAU stated that 20 % of the approximately 400 million people living in 51 African countries is under the age of 5, which is the age of immunization. According to him at present 80-100 million children should be vaccinated annually in Africa. Because of the dimension of the problem, he suggested to consider the feasibility of different approaches when developing project concepts for vaccine production in Africa, namely national versus regional/subregional projects and private versus governmental projects. He emphasized that any combination of the above variables e.g. private companies with government subsidy or joint ventures of private and governmental sectors, could be economically viable under specific conditions.

30. A member, while summarizing the discussions of the Model Programme, expressed that the marketing ability, as a further criterion, should be added to the three main pre-requisites for the successful transfer of technology given in para 33 of the Report on the First Meeting of the Panel (UNIDO/IO. 583, p. 10).

Another member stressed the importance of a more elaborated general introduction, which should clearly explain the dual purpose of the Model Programme. The Panel agreed that the political and public relations aspects of this document are equally important as the technical ones.

31. The UNIDO Secretariat presented to the Panel the project document UC/GLO/84/118 - "Programme and Requirements for Production of Biologicals in Developing Countries". The programme based on this survey will be complementary to the Model Programme and will enable UNIDO to develop technical assistance projects for vaccine production. It was noted that forthcoming projects will not necessarily be implemented in those developing countries included in this survey, since they will be regarded as representative model countries for the regions. The above survey should be carried out since this will result in a programme including all the requirements for such projects and would be confronted with the Model Programme checking its feasbility vis-a -vis its application in developing countries at different stages of industrial development, particularly in the pharmaceutical sector.

32. The UNIDO Secretariat presented the Executive Summary of a survey carried out to assess the existing production facilities for vaccines in Africa (UC/RAF/83/088). It was noted that this survey entitled "Programme for Production of Vaccines in Africa" had been carried out by the Joint UNIDO/Hungary Programme for International Co-operation and was not a part of the IPB Programme. Based on the above survey covering ten African countries, namely Algeria, Chad, Ethiopia, Ghana, Kenya, Madagascar, Nigeria, Senegal, Tanzania and Tunisia a programme had been outlined with recommendations for promoting, rehabilitating, strengthening and expanding the existing vaccine production units in Africa. UNIDO's concept, is first of all, to promote, protect and rehabilitate the existing units without or with minimum capital investment, secondly, to strengthen and expand the above units and thirdly, to establish new production facilities. This concept seems to be essential, since on one hand, there are ambitious plans for the creation of new production institutions for biologicals and on the other, existing

units of high reputation are facing difficulties because of marketing problems. In several cases the size of the domestic market is hampering increases in production and cultural, logistical and political reasons are obstructing the export even to the neighbouring countries. There is only a single case in Africa where a locally manufactured vaccine is accepted and utilized, namely in the yellow fever vaccine produced by the Institute Pasteur, Dakar, Senegal is used in the national EPI of those west African countries where yellow fever is endemic.

33. The Executive Summary of the Programme for Production of Vaccines in Africa was discussed in depth. The Panel agreed that the survey gives an excellent opportunity to introduce the IPB Programme in Africa by encouraging governments to take an initiative. The representative of OAU noted that the lack of initiative was the consequence of an in - adequate dialogue between promoters and beneficiaries. Another member stressed that projects were not successful because in most cases only the physical capital was transferred without developing an experienced and highly motivated manpower. Without an adequate manpower development, which can be regarded as human capital neither planning nor decision making which are the prerequisites of any programme for vaccine production can be carried out. The Panel also agreed that the experience gained in PAHO with a revolving fund system could not directly be applied in the African region, bur the feasibility of a regional/subregional programme should be analysed. A member of the Panel stressed that besides the regional approach the request for technical assistance submitted by any particular African country should be considered.

34. The Panel discussed the feasibility and the cost-benefit aspects of the final establishment of vaccine production units in Africa. It was agreed that based on the population size of most of African countries the cost-benefit and cost-effectiveness analyses for establishing a new production unit could be negative. However, there could also exist indirect impacts on the transfer of technology such as those on cultural, economic and political aspects of industrial development. A member of the Panel stressed that all market parameters such as political will, access to pharmaceutical products and treatment, level of educa-

tion, purchase power, investment conditions, infrastructure, export possibilities, free market forces, donations, etc. should be taken into account when preparing a feasibility study.

35. Another member stressed that the existing manufacturing units with high quality products should be assisted and protected. Many members had emphasized that such high quality local products should be given preference in the region. Several members of the Panel suggested that existing experienced manpower of the institutions of excellence in Africa could be used as nuclei of training centers for production of biologicals at a regional/subregional level.

36. A member of the Panel suggested that upon request his Government would be in a position of not only providing vaccines at production prices, utilizing the unused capacity of its facilities, but also will be willing to provide a long-term technical assistance experts for projects in Africa.

37. Another member stressed that more emphasis should be given to the purchase of imported vaccines as an intermediate alternative between the donation as a single source of supply and the local production. By having purchased imported vaccines, governments will be actually promoting local production, since the allocated funds at a later stage could be more advantageously for the purchase of domestic products.

38. The representative of OAU recommended a more comprehensive approach to the production of biologicals in Africa including vaccines and sera, blood derivatives and diagnostic reagents. Based on the similarities in the technological processing, he suggested that infusion solutions should also be considered. He emphasized that the Lagos Plan of Action should be taken into consideration by the establishment of an international development plan for the production of biologicals in the African States, which could be implemented at stage-wise.

39. Following the discussions of the situation in Africa, the Latin American members of the Panel offered to prepare an analysis of the most important parameters of their own technological processes comparable to the ones given in the Model Programme. This exercise would provide a useful information to the manufacturers of developing countries for the identification of the existing technological gaps between the leading manufacturers and themselves. Another member of a developing country endorse this offer and stated that he would collect similar data for a UNIDO directory.

40. The Panel requested the Secretariat that the working papers for the forthcoming meeting of the Panel should be sent in advance to the members.

41. The Panel expressed satisfaction on the progress made by the Secretariat in the implementation of the IPB programme. However, it was agreed that to secure further development and successful implementation of the IPB Programme, UNIDO should initiate fund raising activities for an IPB fund. Contributions could be accepted from any sources, taking into account that these agree with the principles of the IPB programme.

42. The Panel agreed that the Third Meeting will be held in Bilthoven, Netherlands from 6 to 7 June 1985.

Annex 1

Terms of Reference of the Advisory Panel on Preventive Medicine

(Industrial Production of Biologicals)

1. INTRODUCTION

1.1 In an endeavour to meet the health needs of the developing countries the United Nations Industrial Development Organization has already embarked upon an extensive programme for the production of therapeutics through technical assistance projects, studies and the system of consultations on the pharmaceutical industry.

1.2 The needs of developing countries for the production of biologicals are now acquiring great urgency. This is reflected by the increased number of requests from developing countries for Technical Assistance in the field of vaccines. Production at national, regional and inter-regional levels of vaccines, especially the conventional ones needed most by the developing countries would ameliorate health conditions and help towards self-reliance.

1.3 Towards this end UNIDO has decided to undertake active technical assistance programmes in the field of industrial production of biologicals. An Advisory Panel on Preventive Medicine is considered essential to provide advice and guidance in this field to UNIDO.

2. COMPOSITION OF THE PANEL - APPOINTMENT OF ITS MEMBERS, THEIR STATUS AND ENTITLEMENTS

2.1 The Panel members would be selected with due regard to geographical distribution from both developed and developing countries and would function in their individual capacities. The Panel will also include representatives of United Nations sister organisations i.e. WHO, PAHO, UNICEF and FAO, who can act as members or as technical advisers. The number of members of the Panel will not exceed 16 and additional experts can be co-opted as members as and when required.

2.2 The members would be appointed by the Executive Director of UNIDO with due consideration to their specialised knowledge and experience in all spheres of activities related to preventive medicine. The duration of their appointment will be determined by the Executive Director.

2.3 The Panel shall meet at least twice a year and as frequently as the exigencies of its work indicate, consistent with the availability of its membership.

2.4 The Panel would elect its Chairman and Vice-Chairman. The servicing of the meetings of the Panel will be entrusted to the UNIDO Secretariat, including the provision of a secretary of the Panel.

2.5 The members of the Panel will be entitled to a round trip economy class air travel and per diem in accordance with the United Nations Regulations.[1]

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[1] This provision does not apply to representatives of international organisations within the United Nations system.

3. PURPOSE AND FUNCTIONS OF THE PANEL

3.1 The Panel should provide guidance on the implementation of the Industrial Production of Biologicals as well as the Recommendations concernig Biologicals made by the Second Consultation on the Pharmaceutical Industry.

3.2 The Panel should provide advice and guidance on those aspects related to the establishment of production facilities for biologicals (human and veterinariy vaccines, blood derivatives and diagnostics) in the developing countries. The Panel shall inter-alia provide advice and guidance on:

(a) Drawing up of a priority list of biologicals for production in developing countries.

(b) Identifying criteria for industrial technology for the production of biologicals by characterising its main technical and economic aspects.

(c) Sources of technology and transfer of technology.

(d) Steps to be taken concerning implementation of the IPB programme such as carrying out of surveys for collection of information, organising meetings, implementing case projects at different techno-economic levels in Africa, Asia and Latin America.

(e) Recommend necessary studies, counterparts and magnitude of financial involvements and possible sources of finance.

(f) Evaluate projects with different levels of requirements and technologicals capabilities for specific countries/sub-regions/ regions.

(g) Oversee the progress of the projects and their execution.

(h) Maintain constant awareness of latest scientific development in the field by disseminating information and exchanging missions.

(i) Prepare an annual overall evaluation of the programme for submission to the Executive Director.

(j) Propose specific guidelines for implementation of the recommendations on the subject given by the Second and following Consultations on the Pharmaceutical Industry.

4. AGENDA AND REPORT OF THE PANEL

4.1 The Secretary of the Panel in consultation with the Chairman, will draft the agenda for each meeting and transmit all relevant documents in reasonable time to members.

4.2 For each meeting the Panel would, with the assistance of the UNIDO Secretariat, draw up a report setting forth its findings, observations and recommendations.

4.3 This draft report shall be approved by the Panel before the end of each meeting and forwarded to the Executive Director. The final report will be adopted at the following meeting.

4.4 All circulation of information will be affected through the Secretary of the Panel.

4.5 The Chairman may submit a general report on the work of the Panel to the Executive Director once a year.

Annex 2

List of Participants

MEMBERS OF THE ADVISORY PANEL

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VATICAN CITY

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